Aducanumab Frequently Asked Questions*

On June 7, 2021, the Food and Drug Administration (FDA) approved Aducanumab (Aduhelm), the first new drug for Alzheimer's disease in almost 20 years. Aducanumab is a medication that may help slow the progression of early stage Alzheimer's disease. Many people living with dementia, families, and care professionals have questions regarding this news. Please see below frequently asked questions and some answers for a better understanding of what to expect with the FDA approval of Aducanumab.

What is aducanumab/Aduhelm?

- Aducanumab or Aduhelm is a new medication given by intravenous (IV) infusion once a month. It does not come in pill or injection forms.
- It is an antibody that binds and removes amyloid plaques from the brain. Plaques are increased in the brains of those living with Alzheimer's disease.
- Aducanumab is the first treatment the FDA has approved that targets these plaques.
- It is approved for use with ALL persons who have been diagnosed with Alzheimer 's disease.
- However, the drug has only been tested in people with very mild Alzheimer's disease or mild cognitive impairment.
- In the two studies that tested Aduhelm/aducanumab (which included a total of 3,286 participants), close to 77% of participants were White and 9% were Asian. Less than 0.1% were Black/African American. Three percent were Hispanic/Latino. One participant across the two studies was American Indian/Alaska Native.
- There is no evidence of benefit for individuals in the moderate to severe stages of Alzheimer's disease or other types of dementia.
- Aducanumab is not a cure for Alzheimer's disease but **may** help slow the progression of the disease.

In the research studies conducted, results indicate a 1-2 point reduction in Alzheimer's disease symptoms compared to placebo. However, it is unclear what, if any, clinical relevance there is to the between-group difference.

Has aducanumab been approved by the Food and Drug Administration (FDA)?

- Yes, the FDA announced on June 7, 2021 that they have approved the drug on a provisional basis.
- Provisional basis means that the FDA has directed Biogen to continue research studies to make sure this medication shows clinical benefit for patients, and that it is safe when given to a large number of individuals.
- These requirements by the FDA are in place because there are still questions about the effectiveness of this medication. We will learn more as these studies are completed.
- The evidence supporting the benefit of aducanumab (Aduhelm) is not entirely clear and some physicians may not want to prescribe it.

How will I receive aducanumab treatments if I am a candidate?

- Aducanumab is administered as an intravenous (using a small catheter in the arm) infusion at a specialized infusion center once a month.
- The infusion is administered over 1-2 hours each month.

How safe is aducanumab?

- People receiving this medication may develop minor or severe allergic reactions and need to be monitored closely during the first few infusions.
- Aducanumab studies show that around 4 in 10 subjects developed small bleeds or swelling in the brain. For most subjects, these side effects did not cause significant symptoms, however, some had headache, confusion/delirium, dizziness, and nausea.
- More serious symptoms were noted in 0.3% of patients. Symptoms resolved in 88% of the subjects. Therefore, **multiple brain scans (MRI) are done while receiving this medication to monitor for bleeding and swelling in the brain. Taking aducanumab requires** monitoring with MRI tests at least twice during the first year.

How do you know if you are a candidate to receive aducanumab?

- We don't yet know all of the criteria that will be required for patients to be eligible to receive aducanumab.
- The medication was tested in individuals in the **early** stage of Alzheimer's disease (mild cognitive impairment or early dementia).
- The FDA label does not require proof of amyloid plaques in order to prescribe. The label does say to "obtain an MRI" within at least one year of prescribing to establish baseline and then suggests two scans in the first year of treatment.
- Patients will be required to undergo multiple MRI scans to monitor for any changes while receiving this medication.

When and where will aducanumab be available through healthcare providers?

- Although aducanumab (Aduhelm) is approved, it is not available yet.
- There are multiple additional steps needed before it becomes available to patients, and many of them are outside of an individual healthcare system's control.
- Healthcare systems anticipate it will **take several months** before it is readily available to be administered.

How much will aducanumab cost?

- The cost of the medication for a year of monthly infusions is estimated to be $56,000 per year.
- Additional costs include the infusion center time and supplies, multiple brain scans, clinical evaluations, and laboratory evaluations.
- Medicare and other health insurance carriers have not yet announced decisions about coverage, so currently, there is no coverage.

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